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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,413	10/29/2001	Rachel Auzely-Velty	215158US0PCT	2391
22850	7590	04/06/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/926,413

**Applicant(s)**

AUZELY-VELTY ET AL.

**Examiner**

Traviss C McIntosh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 is/are allowed.
- 6) ☒ Claim(s) 17-26 and 28-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The Examiner of the U.S. Patent application SN 09/926,413 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623, attn: Examiner Traviss McIntosh.

The Amendment filed October 1, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 17, 28-30, 33-34, and 36 have been amended.

The abstract has been amended and is now deemed proper.

The claim for priority to French patent application FR 99/05460 has been granted due to applicants submission of the certified English translation of the priority document in accordance with 37 CFR 1.55.

Remarks drawn to rejections of Office Action mailed May 1, 2003 include:

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 1<sup>st</sup> paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

112 2<sup>nd</sup> paragraph rejections: have been overcome by applicant's amendments and have been withdrawn.

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102(a) rejection: which has been overcome by the submission of the priority documents (as set forth supra) and has been withdrawn.

An action on the merits of claims 17-36 is contained herein below.

The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

### *Claim Objections*

Claim 18 is objected to because of the following informalities: the claim does not end in a period. Appropriate correction is required.

Claims 20 and 24 are objected to because of the following informalities: the claims state “R<sup>2</sup> represents **the** methyl group”, however defining R<sup>2</sup> as “a methyl group” would be a more favorable way to view the claim. Appropriate correction is required.

Claim 28 is objected to because of the following informalities: the word “wherein” in line 3 of the claim should be after the structure of formula, not before it as the claim currently stands. Appropriate correction is required.

Applicant is advised that should claim 30 be found allowable, claims 33 and 34 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 33 is drawn to an “aqueous solution of nanoparticles of the cyclodextrin derivative as set forth in the claim,

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or an inclusion complex of claim 30". Claim 34 is drawn to an "organized surfactant system comprising the cyclodextrin derivative as set forth in the claim (same as claim 33) or an inclusion complex of claim 30. It is noted, that defining the intended use of the "composition" in the preamble is not seen to distinguish the claims, as they are drawn to the same exact thing, something which comprises the same cyclodextrin derivative or the inclusion complex of claim 30, and are thus seen to be substantial duplicates of claim 30.

### ***Claim Rejections - 35 USC § 112***

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for complexes comprising the compounds as disclosed in claim 32, does not reasonably provide enablement for complexes comprising any hydrophobic molecule as in claim 30 or any steroid, neutrope, bacteriostatic, vitamin, vascular wall tonic, or contrast agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

- (A) The breadth of the claims;

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- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

#### **The breadth of the claims - The nature of the invention**

Claim 30 is drawn to inclusion complexes comprising the compound of claim 30 and a hydrophobic compound. Claim 31 provides that the hydrophobic compound is any steroid, neutrope, bacteriostatic, vitamin, vascular wall tonic, or contrast agent.

#### **The state of the prior art**

Cyclodextrin is known in the art to have a hydrophobic interior and a hydrophilic exterior. This difference between the interior and exterior faces allows the cyclodextrin to act as a host molecule and to form inclusion complexes with guest molecules, provided the guest molecule is of the proper size to fit in the cavity, as seen by Buchanan et al. (US Patent 6,610,671).

#### **The level of predictability in the art**

The examiner acknowledges the probability and predictability that some hydrophobic molecules will indeed fit in the inclusion complex formed by the cyclodextrin, however the art is silent with regard to the predictability that any and every hydrophobic molecule is capable of forming inclusion complexes with the cyclodextrin derivative as claimed.

#### **The amount of direction provided by the inventor**

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The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate in the scope with the instant claims. There is a lack of data and examples which adequately represent the scope of claim as written. The examiner notes, there has not been provided sufficient instruction or sufficient methodological procedures to support the complexes instantly claimed.

**The existence of working examples**

The working examples set forth in the instant specification are directed to methods of making cyclodextrin, and to various inclusion complexes which are capable of forming with the cyclodextrin derivative as claimed. The agents disclosed as being used in the inclusion complexes are those which are set forth in claim 32, and are not seen to be representative of the entire genus of "hydrophobic compounds" or any steroid, neutrope, bacteriostatic, vitamin, vascular wall tonic, or contrast agent. There has not been provided sufficient evidence which would warrant the skilled artisan, to accept the data and information provided in the working examples as correlative proof that an inclusion complex could be formed with any hydrophobic molecule, or any steroid, neutrope, bacteriostatic, vitamin, vascular wall tonic, or contrast agent.

**The quantity of experimentation needed to make and use the invention based on the content of the disclosure**

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the formation of an inclusion complex with any hydrophobic molecule or any steroid, neutrope, bacteriostatic, vitamin, vascular wall tonic, or contrast agent without undue

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experimentation. One skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

Claims 17-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, 28, and 29 define the cyclodextrin compound of formula I wherein  $R^2$  is defined as “an alkyl or aryl group, substituted if applicable”. The examiner is unclear as to the meaning of “**if applicable**”. What are the circumstances which would cause the groups to be substituted, or to not be substituted? Clarity is respectfully requested. moreover, the use of the limitation of “**substituted**” is indefinite. In the absence of the identity of moieties which are intended to be substituted, thus modifying an art recognized chemical core, described structurally or by chemical name, the identity of the moiety intended to effectuate substitution would be difficult to ascertain. In the absence of a distinct delineation said moieties, the claims containing the term “substituted” are not described sufficiently to distinctly point out that which applicant intends as the invention. The claims currently define  $R^2$  as alkyl or aryl groups which are optionally substituted by unknown moieties at unknown times.

Claim 35 recites the limitation “the surfactant is a phospholipid” in the first line. There is insufficient antecedent basis for this limitation in the claim, as claim 34, the claim from which it depends, does not provide that there is a surfactant in the system.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).



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***Allowable Subject Matter***

The following is a statement of reasons for the indication of allowable subject matter: claim 27, which is drawn to a cyclodextrin molecule comprising a specific steroid (being cholest-5-en-3 $\alpha$ -ylamide) attached via a succinylamide linkage to the 6-position of one sugar molecule of the cyclodextrin, is not taught or fairly suggested by the prior art of record.

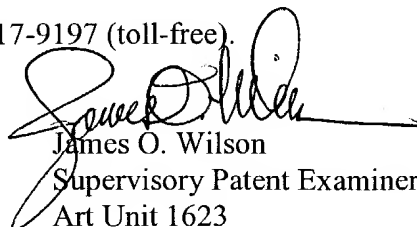
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III  
April 2, 2004

  
James O. Wilson  
Supervisory Patent Examiner  
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